CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-669

CORRESPONDENCE

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

CORRESPONDENCE TO FACSIMILE AMENDMENT
(Dated March 15, 2001)

March 19, 2001

Mr. Charles Hoppes, Director
Office of Generic Drugs
Center for Drug Evaluation & Research
Food & Drug Administration
Document Control Room, MPN II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT

AT

RE: ANDA 75-569 Famotidine Injection – Single Dose 10 mg/mL (2 mL)
ANDA 75-705 Famotidine Injection – Multi Dose 10 mg/mL (4 mL & 20 mL)

Dear Mr. Hoppes,

Faulding is responding to a telephone and facsimile request made by Koung Lee, on March 15, 2001. At that time, Faulding was asked to revise the Famotidine Package Insert according to the Referenced Listed Drug – "Pepcid Injection" approved package insert dated 3/14/01. The below listed revisions have been incorporated into Faulding's final printed package insert..

1. **CLINICAL PHARMACOLOGY SECTION: Pharmacokinetics (sub-section**
   - Revised second paragraph according to the Reference Listed Drug package insert.

2. **PRECAUTIONS SECTION: Patients with Moderate or Severe Renal Insufficiency (sub-section)**
   - Revised subsection heading and the first paragraph according to the Reference Listed Drug package insert.

3. **PRECAUTIONS SECTION: GERIACTRIC USE**
   - Revised the PRECAUTIONS SECTION to include the GERIACTRIC USE subsection and 2 paragraphs.

4. **DOSAGE AND ADMINISTRATION: Dosage Adjustments for Patients with Moderate or Severe Renal Insufficiency**
   - Revised the paragraph according to the Reference Listed Drug package insert.

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
MAR 2 0 2001
OGD

Enclosed are twelve (12) copies of the revised package insert with the requested revisions for your review. Also enclosed is a side-by-side comparison with all differences annotated by the use of color. This side by side amendment has been previously faxed to your attention. If this meets with your approval, please consider this as final printed labeling.

Faulding Pharmaceutical Co. looks forward to your review of this Amendment.

Sincerely,

Iris Feliciano
Regulatory Coordinator
Tel: 908-931-3822
Fax: 908-709-4150

pc: Heike Maaser, Director
enc.

Faulding
A World of Health

Faulding Pharmaceutical Co.
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11 Commerce Drive
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MINOR AMENDMENT

January 17, 2001

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N / Am

Attention: Kassandra Sherrod – Project Manager

RE: **"Minor Amendment for Final Approval"**
ANDA 75-669 – Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose)
2 mL Fill in 2 mL Vials

Dear Madam/Sir:

Reference is made to Faulding's Tentatively Approved ANDA for Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose), 2 mL fill in 2 mL vials (ANDA 75-669). The tentative approval for this ANDA was granted by the agency on December 13, 2000.

The reference listed drug product upon which Faulding's ANDA is based was subject to a period of patent protection until October 15, 2000. This protection was extended to April 15, 2001 based on the agency granting pediatric exclusivity to the innovator product.

We wish to inform the FDA via this amendment that all Labeling, Chemistry, Manufacturing and Controls data have remained unchanged since tentative approval of this ANDA was received on December 13, 2001. In addition, Faulding is not planning to change any data prior to obtaining final approval for this ANDA.

This amendment contains Form FDA 356h as well as a Field Copy Certification. The archival copy and a review copy is being forwarded to you. The field copy of this amendment is being forwarded to the San Juan District Office in Puerto Rico. We are looking forward to obtaining Final Approval for this ANDA.

Should you have any other questions regarding this submission, please do not hesitate to contact me at (908) 931-3806.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel: (908) 931-3806
Fax: (908) 709-4150

ANDA 75-669

DEC 12 2000

Faulding Pharmaceutical Co.
Attention: Kala Patel
11 Commerce Drive
Cranford, NJ 07016

Dear Madam:

This is in reference to your abbreviated new drug application dated July 9, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Injection, 10 mg/mL, (Preservative-Free), packaged in 2 mL single-dose vials.

Reference is made to your amendments dated October 25, and November 17, 2000.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMP) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Pepcid Injection of Merck Research Laboratories (Merck), is subject to a period of patent protection (U.S. Patent No. 4,283,408). Your application contains a Paragraph III Certification to this patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to patent expiry. This patent was scheduled to expire on October 15, 2000. However, as noted in the current edition of the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", the expiration of this patent has effectively been extended until April 15, 2001. Section 111 of Title I of the Food and Drug

Administration Modernization Act of 1997 (the Modernization Act) created section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits the holder of the new drug application (NDA) for the RLD to obtain an additional six months of marketing exclusivity (pediatric exclusivity). To be awarded this exclusivity, the NDA holder must abide by the terms of the statute and submit data previously requested by the agency relating to the use of the drug product in the pediatric population. Merck has submitted data to the agency to support the use of famotidine in the pediatric population. The agency's Pediatric Exclusivity Board has reviewed the data. As a result, the agency has awarded Merck 6-months of pediatric exclusivity. Therefore, final approval of your application may not be made effective until the expiration of the '408 patent on April 15, 2001.

Because the agency is granting a tentative approval to this application, please submit an amendment at least 60 days (but not more than 90 days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and/or controls data as appropriate. An amendment should be submitted even if none of these changes were made. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either, or if requested both amendments may result in rescission of the tentative approval status of your application, may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to agency review before final approval of the application will be made.

If you have questions concerning the status of this application, please contact Kassandra Sherrod, R.Ph., Project Manager, at (301) 827-5849.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

12/12/00

DIVISION REVIEW SUMMARY

ANDA: 75-669

DRUG PRODUCT: Famotidine Injection Single Dose

FIRM: Faulding Pharmaceutical Co.

DOSAGE Injection

STRENGTH: 10 mg/mL

CGMP STATEMENT/EIR UPDATE STATUS:
Acceptable

BIO INFORMATION:
The Division of Bioequivalence have found the application to be acceptable. Waiver granted on 8/23/99 by H.Nguyen.

VALIDATION-DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S)
Methods validation packages sent to Phila DO (Wayne Smith) for drug product only. Accetpable for this and companion ANDA #75-705 on 12/6/99.

STABILITY-ARE CONTAINERS USED IN THE STUDY IDENTICAL TO THOSE USED IN THE CONTAINER SECTION?
LABELING
The future stability protocol the firm proposes is as follows:

Test	Limit
Appearance	
pH	
Assay	
Related Substance	

Sterility

Bacterial Endotoxin

Particulate Matter

The firm included 3 months of accelerated data (25°C ± 2°C) in the proposed container and 3 months of refrigerated 2-8°C data for lot #98S008. Particulate Matter, Sterility and Endotoxin testing will be performed using reduced testing stations. Data were collected in the upright and inverted container orientations. The firm proposes a 24 month expiration dating period with storage at 2-8°C.

The firm also performed some comparative stability testing using the reference listed drug (Pepcid) Merck's product (Attachment 66). They found that the impurities were comparable with Famotidone and Famoacidamine at higher than normal levels for both products. Also Assay testing was performed between both products (potency remained within specification for both products). Also included were freeze-thaw data.

The firm performed a compatability admixture study using the 6 commonly used diluents proposed on the label. Admixtures of the

The admixtures were tested for assay, related compounds, pH and visual inspection and aborbance at 400 nm and 600 nm for a period of 7 days at room temperature (25 ± 2° C). Comparison with Merck's product was also made. Solutions were stable for 7 days.

Also included is a future stability commitment in accordance with FDA Guidelines.

LABELING
The labeling review is acceptable as of 11/21/00 by K.Lee.

STERILIZATION VALIDATION
Acceptable as of 10/23/00 by P.Deleo.

Page(s) 1

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

11/27/00

PROPOSED PRODUCTION BATCH-MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?
Blank batch records are included for future production batches. The maximum intended production size is
Essentially the 2 batch records are the same with the same equipment. A reprocessing statement is also included.

RECOMMENDATION: Approve

SIGNATURE: K Bernard 12/4/00
B Yeomans 12/4/00

DATE: November 27, 2000

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

TELEPHONE AMENDMENT

November 17, 2000

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/A M

RE: "TELEPHONE AMENDMENT IN RESPONSE TO CHEMISTRY DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL, 2 mL Single Dose Vial

Dear Mr. Buehler:

As per the telephone conversation with Mark Anderson today, Faulding Pharmaceutical Co. is submitting this Telephone Amendment. Reference is also made to Faulding's "Minor Amendment" dated October 26, 2000 in which we had provided revised specifications for Famotidine, USP.

Based on the discussion with Mark Anderson, Faulding is hereby submitting new revised specifications for Famotidine, USP (**Attachment 1**). We have tightened the specification for the impurity,

The information in this amendment is being provided to you directly via fax (301) 443-3839. Our complete response, which includes an archival copy and a review copy, has been forwarded to the Food and Drug Administration at the above address under separate cover via UPS overnight courier.

The field copy is being forwarded to FDA's San Juan District Office. Faulding certifies that the field copy is a true copy of the technical sections provided in the review and archival copies of this submission. The field copy certification is provided in **Attachment 2**.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3821.

Sincerely,

K Patel

Kala Patel, M.S., R.Ph.
Manager, Regulatory Affairs
Tel: (908) 931-3821
Fax: (908) 709-4150

RECORD OF TELEPHONE CONVERSATION/MEETING

Ms Patel returned a call I had placed earlier. I said I was asked to call regarding their 10/25/00 amendment to their Famotidine applications.
Regarding their proposed limit for [redacted], I asked if this was the limit that [redacted] had told Faulding that [redacted] had agreed to meet for their API.
Ms. Patel said that [redacted] informed them the limit was [redacted] but that Faulding had proposed [redacted] since they would be using a different method than used by [redacted] which may report the limit as [redacted] i.e. [redacted] She asked if we would accept a limit of [redacted] I said it was my understanding that [redacted] could not be exceeded since this was based on a safety consult.
She said she understood and then agreed to set the limit at [redacted] She said she would amend the applications accordingly. (Fax with hard copy to follow.)
She asked if micro reviews had been completed and I said they had and appeared to be acceptable.
She said she was aware of pediatric exclusivity issue (thus expecting TA letters)
This concluded the conversation

DATE
11/17/00

ANDA NUMBER
75-705
~~75-669~~

IND NUMBER

TELECON

INITIATED BY _ **APPLICANT/ SPONSOR** X **FDA**

MADE X **BY TELE.** _ **IN PERSON**

PRODUCT NAME
Famotidine Inj

FIRM NAME
Faulding

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Karla Patel
DRA

TELEPHONE NUMBER
908-931-3821

SIGNATURE
Mark Anderson

Faulding
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Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

noted pg
10/31/00

VIA UPS OVERNIGHT COURIER

MINOR AMENDMENT

October 25, 2000

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/Am

RE: "RESPONSE TO CHEMISTRY DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL Single Dose Vial

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency facsimile dated October 19, 2000 in which you requested additional CHEMISTRY information. Reference is also made to Faulding Pharmaceutical Co.'s abbreviated new drug application 75-669, dated July 9, 1999. The request for additional information has been defined as a "Minor Amendment" by the agency.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. CMC: Agency's comments, followed by Faulding's response and any attachment(s) for the response
3. Field Copy Certification

This response, which includes an archival copy, a review copy and a field copy, has been forwarded to the Food and Drug Administration via UPS overnight courier.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3821.

Sincerely,

Kala Patel

Kala Patel, M.S., R.Ph.
Manager, Regulatory Affairs
Tel: (908) 931-3821
Fax: (908) 709-4150

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 27 2000
OGD

10/30/00

Faulding
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Telephone (908) 709 1200
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noted pg
10/31/00

VIA UPS OVERNIGHT COURIER

MINOR AMENDMENT

October 25, 2000

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/Am

RE: "RESPONSE TO CHEMISTRY DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL Single Dose Vial

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency facsimile dated October 19, 2000 in which you requested additional CHEMISTRY information. Reference is also made to Faulding Pharmaceutical Co.'s abbreviated new drug application 75-669, dated July 9, 1999. The request for additional information has been defined as a "Minor Amendment" by the agency.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. CMC: Agency's comments, followed by Faulding's response and any attachment(s) for the response
3. Field Copy Certification

This response, which includes an archival copy, a review copy and a field copy, has been forwarded to the Food and Drug Administration via UPS overnight courier.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3821.

Sincerely,

Kala Patel

Kala Patel, M.S., R.Ph.
Manager, Regulatory Affairs
Tel: (908) 931-3821
Fax: (908) 709-4150

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 27 2000
OGD

10/30/00

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

Faulding
A World of Health

noted jrs 9/25/00

VIA UPS OVERNIGHT COURIER

MINOR AMENDMENT

September 21, 2000

NDA ORIG AMENDMENT
N/Am1

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: "RESPONSE TO CHEMISTRY and MICROBIOLOGY DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL Single Dose Vial

Attention: Kassandra Sherrod

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency facsimile dated August 25, 2000 in which you requested additional CHEMISTRY and MICROBIOLOGY information. Reference is also made to Faulding Pharmaceutical Co.'s abbreviated new drug application 75-669, dated July 9, 1999. The request for additional information has been defined as a "Minor Amendment" by the agency.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. CMC: Agency's comments, followed by Faulding's response and any attachment(s) for the response
3. Microbiology: Agency's comments, followed by Faulding's response and any attachment(s) for the response
4. Field Copy Certification

This response, which includes an archival copy, a review copy and a field copy, has been forwarded to the Food and Drug Administration via UPS overnight courier.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3806 and/or Fax (908) 709-4150.

Sincerely,

FAULDING PHARMACEUTICAL CO.

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
SEP 22 2000
OGD

AM 9-25-00

Faulding
A World of Health

Faulding Pharmaceutical Co.
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11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

FAX AMENDMENT

June 30, 2000

ORIG AMENDMENT
N/FA

Mr. Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: "RESPONSE TO CHEMISTRY and LABELING DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL Single Dose Vial

Attention: Kassandra Sherrod

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency facsimile dated June 16, 2000 in which you requested additional CHEMISTRY and LABELING information. Reference is also made to Faulding Pharmaceutical Co.'s abbreviated new drug application 75-669, dated July 9, 1999. The request for additional information has been defined as a "Fax Amendment" by the agency.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. CMC: Agency's comments, followed by Faulding's response and any attachment(s) for the response
3. Field Copy Certification
4. Labeling: Agency's comments, followed by Faulding's response and any attachment(s) for the response

This response, which includes an archival copy, a review copy and a field copy, has been forwarded to the Food and Drug Administration via fax and under separate cover by Federal Express. To amend our method validation information, our response to FDA's comment 3 has also been forwarded to the Method Validation Laboratory in Philadelphia, (Attention: Wayne Smith).

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3806 and/or Fax (908) 709-4150.

Sincerely,

FAULDING PHARMACEUTICAL CO.

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs

Faulding
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11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

June 30, 2000

NEW CORRESP
NC

METHOD VALIDATION

Mr. Wayne T. Smith
Food and Drug Administration
U.S. Customs House/Rm. 900
2nd and Chestnut Streets
Philadelphia, PA 19106-2973

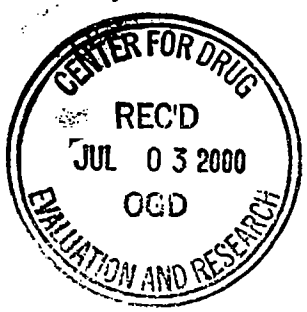
Re: Abbreviated New Drug Application, #75-669
Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose)
2 mL Fill in 2 mL Vials

Amendment to Method Validation

Dear Mr. Smith:

In accordance with 21 CFR 314.71(b) as amended in the Federal Register, Volume 58, No. 172, Faulding Pharmaceutical Co. is hereby submitting three (3) copies of an amendment to our method validation package for our Abbreviated New Drug Application, No. 75-669, Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose), 2 mL Fill in 2 mL Vials.

Faulding Pharmaceutical Co. did receive a fax amendment from the reviewing chemist which included a comment (Comment 3) regarding our Analytical Test Method No "Determination of Related Compounds in Famotidine Injection, 10 mg/mL Single Dose by ". We are, hereby, submitting as an amendment to our Method Validation Package, the response to this comment and a revised Test Method for the determination of Related Compounds. This method No. is identical to the previous one, except that, as discussed in our response, the values included in the test method provided in our ANDA were actually the estimated values determined during pre-validation studies. We have corrected this error and are providing you with the updated method. Since the correct values were used for calculations in our method validation package and for the exhibit batch stability studies, no other corrections need to be made. Faulding apologizes for this error and for any inconvenience this may have caused your laboratory.



Faulding
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Facsimile (908) 709 4150

AMENDMENT TO MAJOR AMENDMENT of February 10, 2000

May 31, 2000

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

MAJOR AMENDMENT

Attention: Kassandra Sherrod

RE: "AMENDMENT TO February 10, 2000 RESPONSE TO MAJOR CHEMISTRY DEFICIENCIES" Abbreviated New Drug Application No. 75-669 Famotidine Injection, 10 mg/mL Single Dose Vial

Dear Madam/Sir:

Faulding Pharmaceutical Co. would like to amend their response to the deficiency facsimile received February 1, 2000, defined as a "Major Amendment" by the Food and Drug Administration Office of Generic Drugs. Faulding responded to this deficiency on February 10, 2000.

In a subsequent telephone conversation on March 21, 2000 with Dr. Vilayat Sayeed and Dr. Florence Fang, it was mentioned that our response to one of the deficiency questions could possibly still be found deficient if we had not submitted data. We, therefore, would like to amend our response. Revised information to your **Comment No. 10** deficiency is provided in Attachment 1.

In addition to this, we would like to provide you with revised drug product specifications for our Famotidine Injection, 10 mg/mL, Single Dose Vials. In our original submission, we erroneously listed the specification for "Description" as "clear, colorless to pale yellow solution". Based on the innovator's FDA approved package insert (PI047/FI September 1999) for Pepcid® (Famotidine Injection), this should read "Clear, colorless solution". We are, therefore, revising our drug product specifications to comply with this. The new specifications (QA 8084-5) are provided in Attachment 2. We apologize for the error.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. Attachments
3. Field Copy Certification

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUN 0 1 2000
OGD

We are, hereby, providing an archival and a review copy. The field copy has been forwarded to the San Juan District Office. We are looking forward to your review of this information in conjunction with our previously submitted responses (February 10, 2000) to your deficiency letter of February 1, 2000.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3806 and/or Fax (908) 709-4150.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

Faulding
A World of Health

CONTROLLED CORRESPONDENCE

APPEAL TO CHANGE MAJOR AMENDMENT STATUS TO MINOR

February 10, 2000

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NEW CORRESP

Project Manager: Ms. Kassandra Sherrod

RE: ANDA 75-669 Famotidine Injection, 10 mg/mL – Single Dose

Dear Madam/Sir:

Faulding Pharmaceutical Co. is referencing the most recent response to a "Major Amendment", dated February 10, 2000. The deficiency letter was issued by FDA February 1, 2000 and requested CHEMISTRY and additional LABELING information. Reference is also made to Faulding Pharmaceutical Co.'s original abbreviated new drug application 75-669, dated July 9, 1999.

At this time, Faulding would like to request that FDA reconsider the status of this amendment and change it from Major to Minor. The reasons for this request are discussed below.

Based on FDA's definition of when amendments are classified as major or minor, as provided for in the Guidance for Industry – Major, Minor, Fax, and Telephone Amendments to Original ANDAs, issued in August 1999, Faulding feels that the current amendment should have been classified as Minor, despite the fact that 12 questions were asked.

Most of the information requested (see details below) was already present in the ANDA, was erroneously identified as a deficiency, and/or the reviewer required explanations and/or had comments, which should not be considered deficiencies.

The information provided in our response, and not already present in the ANDA, consist of a few paragraphs and will not require an experienced reviewer more than one hour for review, FDA's definition for a Major Amendment.

On the following page is a summary of the information requested in the 12 questions marked as a "Major Deficiency" by the reviewer. Attached to this letter are also FDA's comments and Faulding's responses.

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
FEB 14 2000
OGD

1 Copy

Two of the questions (questions 1 and 11) requested new data, tightening of release specifications and identification of the function of the three excipients in the formulation.

Two of the questions (questions 4 and 8) ask for an explanation of information present in the ANDA. Even if this would be interpreted as a borderline deficiency, which we believe it is not, no new data is required, especially in the case of comment 4, which simply asked to identify what is to be done with a batch if in-process pH specifications are not met. No provisions are made for rework in this ANDA, nor are there any pH adjusting agents present in the formula. Therefore, it should be apparent that a failure to meet approved specifications results in destruction of the batch, which is required by cGMPs.

One question (question 2) is a recommendation, probably based on the reviewers impression that bioburden is not controlled since the bioburden limit provided for the bulk solution was overlooked, although present in the ANDA (page 396 and 397) and now also identified in our response.

The tight limits . on the bulk solution drug product, prior to _ takes into account not only the bioburden of all ingredients, but also provides a measure of assurance that environmental controls in the controlled manufacturing areas are effective.

However, even if this question would be considered a deficiency, together with questions 1 and 11, this would still not bring the information presented to the level of a "Major Deficiency".

Four questions (question 5, 6, 7, and 9) requested information already present in the original ANDA. We identified this in our response.

Three questions (question 3, 10, and 12) were erroneously identified as deficiencies. The questions may reflect a reviewer's preference, but these are not FDA requirements. If the reviewer provides a preference, but it does not represent a deficiency, these comments should not be considered in the major/minor determination.

The nitrogen used in the manufacturing process of making Famotidine was identified correctly based on the data presented in the ANDA (question 3).

The "recommendation" for oxygen testing in the headspace (Comment 10) is not a customary industry practice, nor has this ever been a routine requirement by FDA. This is not a deficiency.

The validation data requested for the assay method (LOD and LOQ) is not a requirement for a potency test based on the ICH "Guideline for Industry for Validation of Analytical Procedures" (question 12).

Additionally, this question has never been raised during review in any of the ANDAs previously submitted to and approved by FDA. Therefore, if this question were allowed to stand as a deficiency, it would appear that new requirements are being imposed on industry without publicly disclosing new requirements or standards for applications.

To summarize:

1. one question asks for tightening of specifications;
2. one question asks for identification of function of the three exciepient in the formulation;
3. one question asks for what would be done with a batch if in-process specifications are not met;
4. one question asks to add osmolality specifications as in-process specification (specifications are provided for release) even though in the ANDA it is identified that this test will not be done for commercial product (page 259);
5. one question asks for bioburden limits for raw material;
6. seven questions should not be part of this deficiency letter at all, either as comment or deficiency, since four ask for material already present in the ANDA, and three are erroneously identified as deficiencies.

Even if 5 of the 12 questions were identified as legitimate deficiencies, it is Faulding's sincere belief, and I hope that the agency will concur, that review of this information will not take an "experienced reviewer" longer than one hour. Faulding, therefore, requests that the Status of this Major Deficiency regarding our ANDA 75-669 Famotidine for Injection (Single Dose) 10 mg/mL be changed to a Minor Deficiency since the Major Status appears to be based more on the number of deficiencies, rather than their content and/or on oversights.

Additionally, we would like to request that the deficiency letter about to be issued for our ANDA No. 75-705, Famotidine for Injection (Multidose) 10 mg/mL, be also issued as a Minor Deficiency. In our telephone conversation with the reviewing chemist on February 9, 2000, we were informed that similar questions would be issued for the Multidose ANDA.

We are looking forward to a favorable response to this request. Should you have any questions, please feel free to contact me at the telephone number provided below.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel. (908) 931-3806
Fax (908) 709-4150

c: Dr. Brenda Arnwine, Team Leader

Faulding
A World of Health

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11 Commerce Drive
Cranford, New Jersey 07016
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MAJOR AMENDMENT

February 10, 2000

Mr. Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N|AC

RE: "RESPONSE TO CHEMISTRY and LABELING DEFICIENCIES"
Abbreviated New Drug Application No. 75-669
Famotidine Injection, 10 mg/mL Single Dose Vial

Dear Mr. Sporn:

Faulding Pharmaceutical Co. is responding to your deficiency facsimile dated February 1, 2000 in which you requested CHEMISTRY information and additional LABELING information. Reference is also made to Faulding Pharmaceutical Co.'s abbreviated new drug application 75-669, dated July 9, 1999.

The request for this information has been defined as a "Major Amendment" by the Food and Drug Administration, Office of Generic Drugs. Faulding would like to inform you that we have submitted a request, under separate cover, for reconsideration of the status of this amendment.

For ease of review, Faulding has arranged the response to the current amendment as follows:

1. Form FDA 356h
2. Table of Contents
3. Table of Attachments
4. CMC: Agency's comments, followed by Faulding's response and any attachment(s) for the response
5. Field Copy Certification
6. Labeling: Agency's comments, followed by Faulding's response and any attachment(s) for the response

We have provided an archival copy, a review copy and a field copy for this response. We are looking forward to your review of this Amendment.

If you have any questions regarding this submission, please do not hesitate to contact me at Tel. (908) 931-3806 and/or Fax (908) 709-4150.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
FEB 11 2000
OGD

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VIA UPS OVERNIGHT COURIER

July 9, 1999

Mr. Douglas Sporn, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

505(j)(2)(a)
Paras Patel

Re: Abbreviated New Drug Application
Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose)
2 mL Fill in 2 mL Vials

Original Application

Dear Mr. Sporn,

In accordance with the regulations as promulgated under Section 505(j) of the Federal Food, Drug and Cosmetic Act, as amended, Faulding is submitting this Abbreviated New Drug Application (ANDA) for Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose), 2 mL Fill in 2 mL Vials.

The reference listed drug Pepcid® (Famotidine) Injection, 10 mg/mL is manufactured by Merck & Co., Inc. in single dose (2 mL vials) and multidose (4 mL and 20 mL vials) presentations. This ANDA submission is for single dose (2 mL vials) presentation only. Faulding pharmaceutical Co. will file a separate ANDA for the multidose (4 mL and 20 mL vials) presentations.

Famotidine Injection, 10 mg/mL (Preservative Free, Single Dose), 2 mL Fill in 2 mL Vials is an aqueous concentrated sterile solution for intravenous injection. Its composition is qualitatively and quantitatively the same as the single dose reference listed drug product (2 mL vials) presentation.

If you have any questions concerning this submission, please contact me directly at (908) 931-3806.

Sincerely,

FAULDING PHARMACEUTICAL CO.

K N Patel
for Heike Maaser, Ph.D.
Director, Regulatory Affairs